REMARKS

Claims 1-22 were pending prior to this Response. By the present communication, claims 23-26 were added, claims 1-4, 6, and 16-22, formerly withdrawn due to restriction requirement, have been cancelled, and claims 5, 7, 8, and 9 have been amended. The amendments add no new matter, being fully supported by the specification and original claims. Upon entry of the amendments, claims 5, 7-15 and 23-26 will be pending. Claims 5 and 10 were previously allowed.

The Rejection Under 35 U.S.C. § 112, First Paragraph

Applicants respectfully traverse the rejection of claims 8 and 11-15 under 35 U.S.C. § 112, first paragraph, as allegedly lacking an adequate written description for any nucleic acid comprising at least 15 continuous bases and that hybridizes "under highly stringent conditions" to a polynucleotide having an amino acid sequence as set forth in SEQ ID NO:2 or 4 or to a polynucleotide having a sequence set forth as SEQ ID NO:1. The Examiner asserts in support of the rejection that "if the reference sequences [the polynucleotides of (a)-(e)] contain undefined sequence or differ significantly from the sequences disclosed in the specification, the claims are construed to encompass sequence that has little or no structural similarity to the disclosed sequence" (Office Action, page 5). However, the invention fragments, as defined by amended claim 8, are required to consist of a 15 base segment of a known polynucleotide sequence fully described by nucleic acid or amino acid sequence. In addition, the invention fragments are required to "specifically hybridize" under stringent conditions to a polynucleotide whose sequence is specified or that encodes an amino acid whose sequence is specified. Thus, Applicants disagree with the Examiner's assertion that the structure of the probe is unknown and the structure of the reference polynucleotide is unknown. The structure of each is known and described by the specification.

The function of the invention fragments as probes for identifying polynucleotides encoding Claspin polypeptides or as containing an epitope of a Claspin polypeptide has already been acknowledged by the Examiner. Thus, Applicants submit that the invention isolated fragments possess the nexus of structure and function required under the Description Guidelines.

In addition, Applicants disagree with the Examiner's assertion regarding the description of "highly stringent" conditions in the Specification that claims limited to "highly stringent" conditions are "construed according to their broadest reasonable interpretation, to encompass nucleic acids having low homology with the disclosed nucleic acids" (Office Action, page 6). Applicants submit that this interpretation would not appear to be reasonable to the extent that the "low homology" contemplated by the Examiner would not result in "specific hybridization". In this respect, it is submitted that the skilled artisan would understand the term "specifically hybridize" or "specific hybridization" to mean that an oligonucleotide (e.g., a probe) can be used to identify the presence a target nucleic acid molecule when present among other "non-target" nucleic acid molecules. For example, those of skill in the art would understand that "the term "specifically hybridize" refers to the ability of an invention oligonucleotide (or polynucleotide) probe to hybridize to a polynucleotide sequence as recited in claim 8, but not to a highly related nucleotide sequence or to a sequence of "low homology" as asserted by the Examiner. Hybridization of the oligonucleotide to a sequence of low homology generally will not be above background, or, if some hybridization occurs, is at least about ten-fold less than the amount of hybridization that occurs with respect to the target polynucleotide.

Thus, while the skilled artisan would know many different reaction conditions (e.g., reaction conditions using SSC/0.1% SDS and performed at relatively lower temperatures, or conditions lacking SDS but performed at relatively higher temperature) that similarly provide specific hybridization conditions, it is submitted that it would be improper to consider the term "specific hybridization" to include "hybridization to molecules of low homology" or to consider "highly stringent conditions" to include conditions that would not be considered sufficient for specific hybridization.

Therefore, Applicants submit that the invention polynucleotide fragments are described by a nexus of structure and function such that it would be clear to a skilled artisan, viewing the specification, that Applicants were in possession the common attributes or features of the elements possessed by members of the claimed genus of fragments. Accordingly, Applicants respectfully

request reconsideration and withdrawal of the rejection of claims 8 and 11-15 under the description requirement of 35 U.S.C. § 112, first paragraph.

The Rejection Under 35 U.S.C. § 102(b)

A. Applicants respectfully traverse the rejection of claims 8 and 11-15 under 35 U.S.C. § 102(b) as allegedly being anticipated by Goodearl et al. (June 1999) WO 99/28470 (hereinafter "Goodearl"). Applicants submit that the invention isolated polynucleotide fragments, as defined by amended claim 8, distinguish over the disclosure of Goodearl by "consisting of "a 15 continuous base segment of a polynucleotide selected from the group consisting of:

(a) a polynucleotide encoding a polypeptide consisting of an amino acid sequence as set forth in SEQ ID NO:2 or SEQ ID NO:4;

(b) a polynucleotide of (a), wherein T can be U;

(c) a polynucleotide complementary to (a) or (b);

(d) a polynucleotide consisting of a nucleotide sequence as set forth in SEQ ID NO:1; and

(e) degenerate variants of (a), (b), (c) or (d)."

Applicants disagree with the Examiner's assertion in the Office Action that, as nucleotides 2164 to 2203 of SEQ ID NO:4 are identical to nucleotides 4715 to 4754 of Applicants' SEQ ID NO:1, the nucleic acid molecule of Goodearl is the same as the nucleic acid molecule of claim 8. To stand as a basis of anticipation, a reference must put the public in possession of the invention. Goodearl fails to disclose any 15 nucleotide sequences. In addition, the "consisting of" language of claim 8 requires that the claimed 15 base fragments cannot contain the additional nucleotides of Goodearl's sequence that are not contained in the invention polynucleotide sequences and cannot hybridize to a polynucleotide that would encode other than the exact amino acid sequence of SEQ ID NO:1. Goodearl fails to disclose an amino acid sequence "consisting of" the amino acid sequence of SEQ ID NO:1.

Thus, Applicants respectfully submit that the nucleic acid, host cell, vector and method taught by Goodearl are not the same as those claimed in the present application, despite assertion by the Examiner to the contrary. Since Goodearl fails to disclose each and every limitation of the claims, as

is required to establish anticipation under 35 U.S.C. § 102(b), Applicants respectfully request reconsideration and withdrawal of the rejection over Goodearl.

B. Applicants respectfully traverse the rejection of claims 7 and 9 under 35 U.S.C. 102(e) as allegedly being anticipated by Schlegel et al. (international filing date, 20 February 2001, WO 01/60860; hereinafter "Schlegel"). As grounds of the rejection, the Examiner asserts that Schlegel discloses a nucleic acid "comprising nucleotides 1-4727 [of] the invention polynucleotides having SEQ ID NO:3" (Office Action, page 8). By the present communication, references to SEQ ID NOS:3 and 4 have been deleted from claims 5, 7, 8 and 9 and new claims 23-26, which pertain to these sequences, have been added. Accordingly, the following remarks are with respect to new claims 23-26.

According to the sequence alignment provided by the Examiner, there are two mismatches of the nucleotide sequence of SEQ ID NO:3 within the noted 4727 nucleotides of Schlegel's sequence and, moreover, the complete polynucleotide sequence of the invention polynucleotide having SEQ ID NO:3 contains 4756 nucleotides, not just the 4725 nucleotides in common with Schlegel. Applicants submit, therefore, that the invention isolated polynucleotides and the polynucleotide fragments that "consist of a 15 continuous base segment of and hybridize to . . .", as defined by new claims 23, 24 and 25, distinguish over the disclosure of Schlegel with regard to SEQ ID NO:4, by requiring a 4756 nucleic acid sequence that encodes a polypeptide consisting of an amino acid sequence as set forth in SEQ ID NO:4. Similarly the invention polynucleotides, as defined by new claim 26, distinguish over Schlegel by requiring a polynucleotide that encodes a polypeptide *consisting of* an amino acid sequence as set forth in SEQ ID NO:4. Schlegel fails to disclose such polypeptides and fragments.

To stand as a basis of anticipation, a reference must put the public in possession of the invention. The "consisting of" language of new claims 23-26 requires that the claimed polynucleotides exclude the additional nucleotides of Schlegel's 4804 sequence and Applicants submit that Schlegel fails to disclose selection of any particular polynucleotide segment of the prior art polynucleotide, let alone the particular segments of the Schlegel sequence that the Examiner has asserted anticipates the invention polynucleotides of claims 7 and 9. For example, Schlegel fails to

disclose a polynucleotide *consisting of* nucleic residues 1-331 of SEQ ID NO:3, as is required in new claim 26.

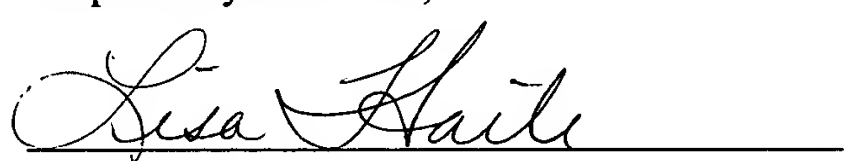
Thus, Applicants respectfully submit that Schlegel fails to disclose each and every limitation of the claims, as is required to establish anticipation under 35 U.S.C. § 102(e), and reconsideration and withdrawal of the rejection over Schlegel are respectfully requested.

In view of the above amendments and remarks, Applicants believe that all claims are now in condition for allowance, which action is respectfully requested.

The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

Respectfully submitted,

Date: July 28, 2004



Lisa A. Haile, Ph.D.
Registration No. 38,347
Telephone: (858) 677-1456
Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP
4365 Executive Drive, Suite 1100
San Diego, CA 92121-2133
USPTO CUSTOMER NO. 28213